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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,899	09/25/2006	Che-Hung Robert Lee	NIH275.001NP	9600
36218	7590	06/25/2010	EXAMINER	
KLARQUIST SPARKMAN, LLP (OTT-NIH) 121 S.W. SALMON STREET SUITE #1600 PORTLAND, OR 97204-2988				SWARTZ, RODNEY P
ART UNIT		PAPER NUMBER		
1645				
			NOTIFICATION DATE	DELIVERY MODE
			06/25/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

tanya.harding@klarquist.com  
docketing@klarquist.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/566,899	LEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29March2010.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-8, 19-22 and 33-39 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8, 19-22 and 33-39 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/2010</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

1. Applicants' Response to Office Action, received 29 March 2010, is acknowledged. Claims 1 and 21 have been amended. New claims 33-39 have been added.
2. Claims 1-8, 19-22 and 33-39 are pending and under consideration.

**Rejections/Objections Withdrawn or Moot**

3. The objection to claim 21 is withdrawn in light of the amendment of the claim.
4. The rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn.
5. The rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, as being indefinite for "reducing substantially all", is withdrawn.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-8, 19-22 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lees (U.S. Pat. No. 5,849,301) further in view of Chu et al, *Infection and Immunity*, 40(1):245-256, 1983).

The claims are drawn to a method of preparing a conjugate vaccine, comprising: 1) reacting a polysaccharide with an oxidizing agent; 2) changing the pH to about 7 to about 8; 3) reacting a protein with hydrazine in the presence of EDC at pH from about 6 to about 7; 4) raising the pH to from about 10 to about 11; 5) reacting the aldehyde activated polysaccharide

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with the hydrazide-activated protein at a pH of from about 6 to about 8; and, 6) reducing the C==N double bonds of the conjugate to C--N single bonds.

Lees teaches a method of preparing a conjugate vaccine, comprising: 1) reacting a polysaccharide from *H. influenzae*, *E. coli*, or *Pneumococcus* with an oxidizing agent; 2) changing the pH to about 7 to about 8; 3) reacting a protein with hydrazine at pH from about 6 to about 7; 4) raising the pH to from about 10 to about 11; 5) reacting the aldehyde activated polysaccharide with the hydrazide-activated protein at a pH of from about 6 to about 8; and, 6) reducing the C==N double bonds of the conjugate to C--N single bonds (Abstract; Table 1; Col. 6, lines 64-66; Col. 8, line 31 to Col. 13, line 21; Col. 13, Chart, lines 25-67).

Lees does not teach reacting the protein in the presence of EDC. Chu et al do teach methods of producing conjugate of polysaccharides from *H. influenzae*, *E. coli*, or *Pneumococcus* with protein by reacting the protein in the presence of EDC in order to increase the efficiency of the coupling reaction (page 247, section **Synthesis of the conjugates**; page 248, section **Efficiency of coupling reaction**).

It would have been obvious to one of skill in the art at the time the invention was made to utilize EDC during the coupling reaction to increase the efficiency of the reaction, as taught by Chu et al.

### Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

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If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

June 23, 2010